U.S. FOOD & DRUG ADMINISTRATION

Welcome to today's
FDA/CDRH Webinar

Thank you for your patience while we register all of today's participants.

If you have not connected to the audio portion of the webinar, please do so now:
U.S. Callers Dial: 888-972-9678
International Callers Dial: 1-630-395-0408

Conference Number: PWXW6320123

Passcode: 2366523

FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions Final Guidance

Ken Skodacek
Policy Analyst
Clinical Trials Program &
Payer Communication Task Force
Office of Device Evaluation
Center for Devices and Radiological Health

- Investigational Device Exemption (IDE)
- Background and Rationale
- FDA Process: Category Criteria & Examples
- CMS Process: Application & Criteria
- Changing the Category
- References, Questions & Answers

IDE Clinical Investigations

- Approved investigational device exemption (IDE) allows device to be used in a clinical study in order to collect safety and effectiveness data.
- Generally, an IDE study is conducted to answer outstanding questions about device safety and effectiveness.
- However, the extent to which initial questions of safety and effectiveness are already addressed depends on many factors.

21 CFR Part 812

IDE Decision-Making Process

Approval of an IDE application indicates FDA has determined:

- Sponsor has provided adequate data to support initiation of the study.
- No subject protection concerns to preclude initiation of the study after Institutional Review Board (IRB) approval.
- Benefit-risk profile for the study is favorable.

FDA's process and considerations outlined in guidance:

- FDA Decisions for Investigational Device Exemption Clinical Investigations
- Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions

- Investigational Device Exemption (IDE)
- **Background and Rationale**
- FDA Process: Category Criteria & Examples
- CMS Process: Application & Criteria
- Changing the Category
- References, Questions & Answers

Background: “CMS Category”

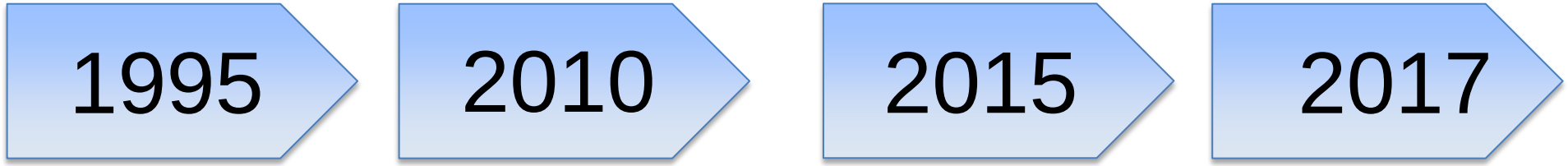
To support the Centers for Medicare and Medicaid Services (CMS), FDA categorizes IDE devices based on whether available data demonstrates that initial questions of safety and effectiveness have been resolved.

IDE applications are assigned to one of two categories:

- Category A - Experimental devices
- Category B - Non Experimental/Investigational devices

FDA communicates this categorization in our regulatory decision letters by assigning a “CMS Category.” CMS uses this categorization as one of several factors in its determination of which devices meet the requirements for Medicare coverage.

Historical Context



FDA & Health Care Financing Administration (now known as CMS) Interagency Agreement

FDA & CMS Memorandum of Understanding (Jun 2010)

Change in Medicare Coverage for IDE's (Jan 2015)

FDA & CMS Memorandum of Understanding (Dec 2015)

FDA Categorization Guidance

Primary Rationale for Guidance

- Previous FDA policy regarding categorization did not adequately articulate criteria that are relevant to certain studies such as feasibility studies.
- Previous criteria did not consider all regulatory pathways (e.g., De Novo request).
- Previous policy did not contain sufficient guidance regarding how a category designation may change from A to B.

Secondary Rationale for Guidance

- CMS changed from local Medicare Administrative Contractor (MAC) review of IDE studies to a centralized review of IDE studies effective January 1, 2015.

- Interactions between FDA and CMS since that time have highlighted a need for changes to categorization in order to improve consistency.

Compare and Contrast

1995 Interagency Agreement	FDA Categorization Guidance	
Detailed criteria were used to designate an IDE device category.	Criteria have been simplified to ensure that devices fall into the correct category.	Changes
Limited or no visibility to how a category change may occur as knowledge is gained.	Final guidance provides an explanation of how a category change may occur.	
No examples provided.	Examples provided.	
FDA review team makes the category designation.	Unchanged	Same (no changes)
Category designation is to be based on the degree to which initial questions of safety and effectiveness are resolved.	Unchanged	
Categorization will then be used by CMS as part of its determination of whether or not items and services will be covered.	Unchanged	

- Investigational Device Exemption (IDE)
- Background and Rationale
- **FDA Process: Category Criteria & Examples**
- CMS Process: Application & Criteria
- Changing the Category
- References, Questions & Answers

IDE Review by FDA: Categorization

Step 1: FDA Process

- IDE application
- FDA review
- Category assigned in IDE approval letter

Category A: Regulatory Context

Experimental

"…a device for which 'absolute risk' of the device types has not been established (that is, initial questions of safety and effectiveness have not been resolved) and the FDA is unsure whether the device type can be safe and effective."

42 CFR 405.201(b)

Category A: 1st Criterion

An IDE is assigned Category A if one or more of the following criteria are met:

"No PMA approval, 510(k) clearance, or De Novo request has been granted for the proposed device or similar devices, and data on the proposed device or other similar devices do not resolve initial questions of safety and effectiveness and FDA is unsure whether the device type can be safe and effective."

- No prior approved/cleared device
- Available data do **not** resolve initial questions of safety and effectiveness

Category A: 2nd Criterion

An IDE is assigned Category A if one or more of the following criteria are met:

"The proposed device is being studied for a new indication or new intended use for which information from the proposed or a similar device related to the previous indication or intended use does not resolve initial questions of safety and effectiveness. Available non-clinical and/or clinical data on the proposed device or similar devices relative to the new indication or intended use also do not resolve these questions and FDA is unsure whether the device type can be safe and effective."

- New indication or new intended use
- Available data do **not** resolve initial questions of safety and effectiveness

Category A: 3rd Criterion

An IDE is assigned Category A if one or more of the following criteria are met:

"The proposed device has different technological characteristics compared to a legally marketed device, and information related to the marketed device does not resolve initial questions of safety and effectiveness for the proposed device. Available non-clinical and/or clinical data on the proposed device or similar devices also do not resolve these questions and FDA is unsure whether the device type can be safe and effective."

- New technological characteristics compared to approved/cleared devices
- Available data do **not** resolve initial questions of safety and effectiveness

Category A: Summary of Criteria

An IDE is assigned Category A if one or more of the following three criteria are met:

- No prior approved/cleared device
- Available data do **not** resolve initial questions of safety and effectiveness

- New indication or new intended use
- Available data do **not** resolve initial questions of safety and effectiveness

- New technological characteristics compared to approved/cleared devices
- Available data do **not** resolve initial questions of safety and effectiveness

Category A: Examples

- Novel device with no or limited previous human use
  - Remaining initial questions of safety and effectiveness.
  - Adequate non-clinical information to support initiation of an early feasibility study.

- New device
  - Initial question of **safety** have been answered with non-clinical data and short-term clinical data.
  - Additional data needed to resolve initial questions of **effectiveness**.

Category B: Regulatory Context

Nonexperimental/Investigational

"…a device for which the incremental risk is the primary risk in question (that is, initial questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval or clearance for that device type."

42 CFR 405.201(b)

Category B: 1st Criterion

An IDE is assigned Category B if one or more of the following criteria are met:

> "No PMA approval, 510(k) clearance, or De Novo request has been granted for the proposed device or similar devices; however, available information (e.g., feasibility study data) from the proposed device or a similar device resolves the initial questions of safety and effectiveness."

- No prior approved/cleared device
- However, available data resolves initial questions of safety and effectiveness

Category B: 2nd Criterion

An IDE is assigned Category B if one or more of the following criteria are met:

> "The proposed device is being studied for a new indication or new intended use; however, information from the proposed or a similar device related to the previous indication or intended use resolves the initial questions of safety and effectiveness. In some cases, additional non-clinical and/or clinical data on the proposed device may also have been used to resolve these questions."

- New indication or new intended use
- However, available data resolves initial questions of safety and effectiveness

Category B: 3rd Criterion

An IDE is assigned Category B if one or more of the following criteria are met:

"The proposed device has similar technological characteristics compared to a legally marketed device, and information related to the marketed device resolves the initial questions of safety and effectiveness for the proposed device. In some cases, additional non-clinical and/or clinical data on the proposed device may also have been used to resolve these questions."

- Similar technological characteristics compared to approved/cleared devices
- Available data resolves initial questions of safety and effectiveness

Category B: Summary of Criteria

An IDE is assigned Category B if one or more of the following three criteria are met:

- No prior approved/cleared device
- However, available data resolves initial questions of safety and effectiveness

- New indication or new intended use
- However, available data resolves initial questions of safety and effectiveness

- Similar technological characteristics compared to approved/cleared devices
- Available data resolves initial questions of safety and effectiveness

Category B: Examples

- Device similar to other devices on the market
  - Substantial safety and effectiveness information exists from other similar devices of the same type that are used for a similar indication.
  - Clinical information from similar devices and non-clinical test data for the new device answer initial safety and effectiveness questions.
- Approved device for a new indication
  - Data exist on the approved device for a similar indication.
  - Non-clinical data also provided to answer initial questions of safety and effectiveness.

- Investigational Device Exemption (IDE)
- Background and Rationale
- FDA Process: Category Criteria & Examples
- **CMS Process: Application & Criteria**
- Changing the Category
- References, Questions & Answers

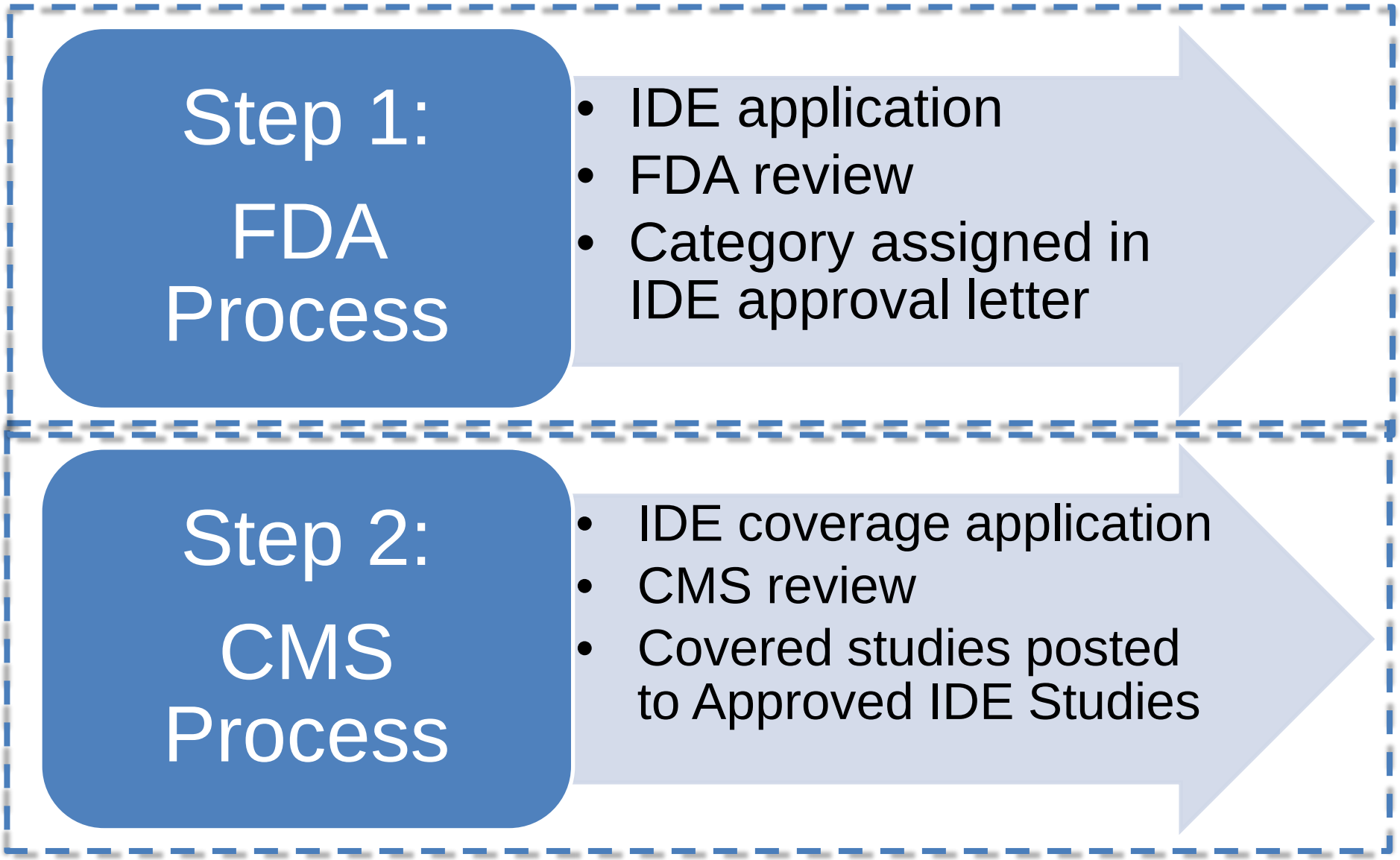
IDE Review by CMS: Decision

Step 2: CMS Process

- IDE coverage application
- CMS review
- Covered studies posted to Approved IDE Studies

Medicare Coverage Related to Investigational Device Exemption (IDE) Studies

IDE Review: Two Step Process



CMS Coverage: Result

Category A (Experimental) IDE

- Approval by CMS will **allow coverage of routine care items and services** furnished in the study, but **not of the Category A device**, which is statutorily excluded from coverage.

Category B (Nonexperimental/investigational) IDE

- Approval by CMS will **allow coverage of the Category B device and the routine care items and services** in the trial.

- Investigational Device Exemption (IDE)
- Background and Rationale
- FDA Process: Category Criteria & Examples
- CMS Process: Application & Criteria
- **Changing the Category**
- References, Questions & Answers

Changing Category: Rationale

- Clinical and/or non-clinical data gathered during the study may resolve initial questions of safety and effectiveness.

- Category A study is completed resolving the initial questions of safety and effectiveness.

Changing Category: Data

Examples of data that may support a change from Category A to Category B can include but are not limited to:

- Peer-reviewed studies on the same or a similar device
- Premarket or postmarket data from studies conducted outside the U.S. on the same or a similar device
- Reference to commercialization of a device of a similar type
- Preliminary clinical data on the device (e.g., initial data from a staged study, feasibility study)
- Additional non-clinical data on the same or a similar device may be included as supportive information

Changing Category: Select Examples

- Approved device with novel procedure
  - Initial unresolved questions of safety and effectiveness regarding the novel procedure
  - Remaining questions may be answered with a limited number of subjects as part of a larger study

- Category A device being evaluated in a study
  - Clinical data for similar devices become available which resolve initial questions of safety and effectiveness

- Investigational Device Exemption (IDE)
- Background and Rationale
- FDA Process: Category Criteria & Examples
- CMS Process: Application & Criteria
- Changing the Category
- References, Questions & Answers

Payer Communication Task Force

- Facilitates early communications between device manufacturers, payers, and healthcare technology assessment organizations to potentially shorten the time between FDA approval or clearance and actual coverage decisions
- Focus on coverage outside of IDE studies
- Coordinates FDA/CMS Parallel Review program
- Coordinates other opportunities for public and private payer engagement

Contact us at:
CDRHPayerCommunications@fda.hhs.gov
Parallel-Review@fda.hhs.gov

References – Page 1

- FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions
- Medicare Coverage Related to Investigational Device Exemption (IDE) Studies
- Medicare Approved IDE Studies
- Change in Medicare Coverage for IDE's
- FDA Decisions for Investigational Device Exemption Clinical Investigations
- Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions

References – Page 2

- FDA/HCFA Interagency Agreement (1995)
- FDA/CMS Memorandum of Understanding (2010)
- FDA/CMS Memorandum of Understanding (2015)
- CDRH Payer Communication Task Force

Questions?

Division of Industry and Consumer Education: DICE@fda.hhs.gov

Slide Presentation, Transcript and Webinar Recording will be available at:

http://www.fda.gov/training/cdrhlearn